J&J-100US

Appln. No.: 10/629,308

Amendment Dated November 19, 2008 Reply to Office Action of August 19, 2008

Amendments to the Claims: This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

1. (**Currently Amended**) A sterile aqueous pharmaceutical composition for parenteral administration of propofol, said composition comprising about 1% (w/v) propofol in combination with and less than 15% (w/v) excipients, said excipients including comprising:

7% to 9% (w/v) poloxamer component consisting essentially of Poloxamer 188;

2% to 4% (w/v) polyethylene glycol; and

not more less than 1% (w/v) lipid,

wherein the composition further comprises less than 5% (w/v) of said excipients comprise not more than 15% (w/v) of said composition and said composition is stored in a container having a means for dispensing the composition, and wherein the total proposol degradants of the solution when maintained at 25 °C, 40 °C, or 60 °C for 4 weeks are present in an amount of less than 5% (w/v) of said composition.

2 - 5. (Canceled)

- 6. (Previously Presented) The composition of Claim 1, wherein said polyethylene glycol comprises polyethylene glycol 400, and wherein said excipients further comprise one or more compounds selected from the group consisting of citric acid, disodium edetate, metabisulfate, benzyl alcohol, propylene glycol, an antioxidant, a preservative, an antimicrobial agent, and a microbicidal.
- 7. (Canceled)
- 8. (Previously Presented) The composition of Claim 1, wherein:
- a) said composition has a particle size diameter of between 25 and 200 nm;
- b) said composition has a particle size diameter of between 50 and 100 nm; or
- c) said composition forms particles of similar particle size.
- 9. (Previously Presented) The composition of Claim 1, wherein:

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- a) said composition does not support microbial growth;
- b) said composition is microbicidal; or
- c) said composition is sufficient for no more than a 10-fold increase in growth, of *Staphylococcus aureus* ATCC 6538, *Escherichia coli* ATCC 8739, *Pseudomonas aeruginosa* ATCC 9027 or *Candida albicans* ATCC 10231 for at least 24 hours.
- 10. (Previously Presented) The composition of Claim 1, wherein:
- a) said composition is functionally bioequivalent to commercial lipid based anesthetic products:
 - (i) wherein said bioequivalence is demonstrated in dogs;
 - (ii) wherein said bioequivalence is demonstrated in humans; or
- b) said composition has a red blood cell blood plasma partition coefficient greater than that of commercial lipid based anesthetic products:
 - (i) wherein said partition coefficient for said composition is between about 2 and 4.
- 11. (Previously Presented) The composition of Claim 1, further comprising:
- a) an acid;
- b) a base;
- c) a local anesthetic;
- d) a second general anesthetic;
- e) an antimicrobial agent;
- f) a surfactant;
- g) a tonicity modifier;
- (i) wherein said tonicity modifier is glycerol;
- h) a pH modifier; or
- j) a second, third, fourth, fifth, or sixth excipient.
- 12. (Previously Presented) The composition of Claim 1, wherein said composition is substantially free of: a. an antimicrobial agent; or b. a preservative.

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13.-24. (Canceled)

- 25. (**Currently Amended**) A sterile aqueous pharmaceutical composition for parenteral administration of propofol, said composition comprising about 1% (w/v) propofol in combination with and less than 15% (w/v) excipients, said excipients comprising including: 7% to 9% (w/v) poloxamer component consisting essentially of Poloxamer 188; 2% to 4% (w/v) polyethylene glycol; 0% to 1% (w/v) propylene glycol; and not more less than 1% (w/v) lipid wherein said excipients comprise not more less than 15% (w/v) of said composition.
- 26. (Previously Presented) The composition of Claim 25, wherein said excipients comprise: 8% (w/v) Poloxamer 188; 3% (w/v) polyethylene glycol 400; and 1% (w/v) propylene glycol.
- 27. (**New**) The composition of Claim 1, wherein said composition is stored in a container having a means for dispensing the composition.